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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,142	10/15/2001	Kazuya Kawasaki	JG-TT-5103 / 500568.20030	4088
26418	7590	05/17/2005	EXAMINER	
REED SMITH, LLP ATTN: PATENT RECORDS DEPARTMENT 599 LEXINGTON AVENUE, 29TH FLOOR NEW YORK, NY 10022-7650			SIEFKE, SAMUEL P	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/978,142	Applicant(s) KAWASAKI ET AL.	
	Examiner Samuel P. Siefke	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Objections

Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 9 states wherein the organic solvent is as is. An organic solvent is an organic solvent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims **3-9** are rejected under 35 U.S.C. 103(a) as being unpatentable over Terashima et al. (USPN 4,900,665).

Terashima discloses a method of producing a multilayer analytical element that comprises a water-impermeable transparent support (col. 3, lines 54-65), at least one water-permeable layer (col. 4, lines 24-56), and a spreading layer which is composed of polyester and has a function of spreading liquid uniformly (col. 6, lines 7-68; col. 9, line 28 and line 51-52), laminated in this order. It is desirable that a self-developing substrate is incorporated in the spreading layer so as not to be brought into contact with a buffering agent in the water-permeable layer. For example, the incorporation of a self-developing substrate in the spreading layer is performed in such a manner that a laminated structure obtained by laminating the water-permeable layer and the spreading layer in turn onto a support as described above is coated or impregnated with a coating solution of the self-developing substrate and optionally a surfactant and a high molecular weight compound dissolved in an organic solvent or a mixture of an organic

solvent and water. Examples of such organic solvents include water-soluble polar solvents such as methanol, ethanol, propanol, acetone and acetonitrile; and hydrophobic solvents such as toluene and ethyl acetate. When the spreading layer is composed of a material to be laminated by lamination, such as woven fabric or glass fiber filter paper, the substrate may be previously impregnated, dried and then laminated. When the spreading layer is formed by coating, for example, the spreading layer is composed of a brushed polymer layer or three-dimensional lattice-form structure using microbeads, the coating solutions for the substrate and the spreading layer may be mixed together and applied. In addition to the self-developing substrate, a light blocking fine particle or reagents such as surfactant may be incorporated into the spreading layer of the analytical element of the invention. These reagents may be mixed with the coating solution for the substrate to incorporate it in the spreading layer, or the reagents and the substrate may be separately incorporated in the spreading layer by other methods. The organic solvent is a lower alcohol containing 1 to 4 carbon atoms (ethanol, acetone, col. 8, lines 35-38). The organic solvent is supplied in an amount of 30 to 90% of the spreading layer by volume (col. 11, lines 10-30; col. 12, lines 43-64). The spreading layer after the organic solvent is dried until the amount of the organic solvent coating becomes 0.1 to 5% of the supplied amount. Terashima discloses allowing ample amount of time to dry, 60 ml m² amount of the solution was added to the spreading layer (col. 11, lines 15-18).

Terashima does not teach supplying an organic solvent not containing a critical reagent onto the spreading layer, and thereafter supplying a reagent solution containing

a critical reagent for an objective analysis while leaving the organic solvent on the surface of the fibers.

Ex parte Rubin, 128 USPQ 440 (Bd. App. 1959) A prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter impregnated with a thermosetting material was held to render prima facie obvious claims directed to a process of making a laminated sheet by reversing the order of the prior art process steps. Therefore it would have been obvious to one having an ordinary skill in the art to modify Terashima to add the self-developing substrate (critical reagent) after adding the organic solvent that comprises the hydrophilic and hydrophobic properties to the spreading layer.

It is noted that a declaration of unexpected results showing analytical results that the present method of producing a dry analytical element produces a test element that exhibits even soaking of a coating solution during the manufacturing process and evenness in color development of the reagent which is unexpectedly superior to the prior art would obviate a prima facie case of obviousness.

A showing of unexpected results must be based on evidence, not argument or speculation.

Response to Arguments

Applicant's arguments with respect to claims 3-9 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P. Siefke whose telephone number is 571-272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sam P. Siefke



May 4, 2005


Jill Warden
Supervisory Patent Examiner
Technology Center 1700